No. __-____

IN THE
Supreme Court of the United States

MARIANNE CHAPMAN AND DANIEL CHAPMAN,
Petitioners,

v.

THE PROCTER & GAMBLE DISTRIBUTING LLC AND
THE PROCTER & GAMBLE MANUFACTURING COMPANY,
Respondents.

On Petition for a Writ of Certiorari to the United States Court of Appeals for the Eleventh Circuit

PETITION FOR A WRIT OF CERTIORARI

RAYMOND C. SILVERMAN
MELANIE H. MUHLSTOCK
MATTHEW J. MCCAULEY
PARKER WAICHMAN LLP
6 Harbor Park Drive
Port Washington, NY 11050
(516) 466-6650

DAVID C. FREDERICK
Counsel of Record
DEREK T. HO
KELLOGG, HUBER, HANSEN, TODD, EVANS & FIGEL, P.L.L.C.
1615 M Street, N.W.
Suite 400
Washington, D.C. 20036
(202) 326-7900
(dfrederick@khhte.com)

February 6, 2015

QUESTION PRESENTED

Under Rule 702 of the Federal Rules of Evidence, expert testimony is admissible if it is "based on sufficient facts or data" and "is the product of reliable principles and methods." In toxic tort cases, litigants routinely offer expert testimony on the issue of "general causation" – the ability of an alleged toxic substance to cause a particular disease. In this case, petitioners offered the opinions of preeminent scientists that ingestion of large amounts of zinc contained in Procter & Gamble's Fixodent-brand denture cream can cause a serious disease known as "copper-deficiency myelopathy." Those opinions were consistent with the widespread consensus in the medical community and were supported by extensive scientific evidence. In a ruling that deepens a five-to-two circuit conflict, the Eleventh Circuit excluded those opinions as unreliable on the ground that petitioners' experts could not produce specific types of epidemiological evidence supporting the causal relationship between Fixodent and copper-deficiency myelopathy. Such epidemiological studies had not been conducted on Fixodent because, for more than two decades, Procter & Gamble had failed to disclose to consumers that it was formulated with a high concentration of zinc. In the First, Third, Fourth, Ninth, and D.C. Circuits, courts would have reversed the district court's grant of summary judgment.

The question presented is:

Whether Rule 702, as interpreted by *Daubert* and its progeny, permits a district court to require epidemiological evidence as a precondition for admissibility of a qualified expert's opinion that a toxic substance is capable of causing a particular disease.

LIST OF PARTIES TO THE PROCEEDING

Petitioners Marianne Chapman and Daniel Chapman were plaintiffs in the district court and appellants in the court of appeals.

Respondents The Procter & Gamble Distributing LLC and The Procter & Gamble Manufacturing Company were defendants in the district court and appellees in the court of appeals.

TABLE OF CONTENTS

TABLE OF AUTHORITIES

CONSTITUTION, STATUTES, AND RULES

OTHER MATERIALS

Petitioners Marianne Chapman and Daniel Chapman respectfully petition for a writ of certiorari to review the judgment of the United States Court of Appeals for the Eleventh Circuit in this case.

INTRODUCTION

In *Daubert v. Merrell Dow Pharmaceuticals, Inc.*, 509 U.S. 579 (1993), this Court held that Federal Rule of Evidence 702 requires admission of expert testimony subject to limited gatekeeping by lower courts to ensure that opinions lacking a reliable scientific foundation are not permitted to confuse the jury. *See id.* at 597. Since *Daubert*, lower courts have been divided on the recurring problem of the admissibility of expert testimony regarding general causation in toxic tort cases – that is, the ability of a suspected toxic agent to cause a particular disease. General causation is almost always the subject of expert testimony, and it is often the central factual dispute between the parties in toxic tort cases.

In the decision below, the Eleventh Circuit, adhering to prior circuit precedent, held that an expert's opinion on general causation is not reliable unless it is supported by specific types of epidemiological evidence – the dose-response relationship between the toxic agent and the disease, evidence of statistically significant association based on analytical epidemiological studies, and the background risk of disease in the general population. Calling these forms of evidence "indispensable to proving the effect of an ingested substance," App. 18a, in the Eleventh Circuit, the court deemed the other scientific evidence relied on by petitioners' experts "insufficient" and affirmed the exclusion of their general causation opinions.

Certiorari is warranted because the decision below deepens an existing circuit conflict on the question

whether epidemiological evidence is required for an admissible expert opinion on general causation under Rule 702. In direct conflict with the Eleventh Circuit, five other circuits have held that epidemiological evidence is not "indispensable." Those courts have emphasized that a rigid rule requiring epidemiological evidence is inappropriate because such evidence is often unavailable for novel toxic substances or rare diseases. By contrast, the Fifth Circuit had held even before *Daubert* that epidemiological evidence is required, and since *Daubert* it has continued to exclude general causation opinions on that basis. The decision exacerbates that conflict and warrants this Court's review.

This Court's intervention is also warranted because the Eleventh Circuit's legal test contravenes *Daubert* and its progeny. As this Court has made clear, given the "liberal thrust" of the Federal Rules, the gatekeeping role of federal courts under Rule 702 is necessarily limited. Although parties should not be permitted to present "junk science" to the jury, Rule 702 contemplates that juries, not courts, are better positioned to decide which of two competing expert opinions is correct, after each side's expert is subjected to cross examination and the adversarial process.

The Eleventh Circuit's rigid requirement of epidemiological evidence is contrary to that limited gatekeeping function. Epidemiological evidence is sometimes said to be the "gold standard" of causation evidence. As the majority of circuits have held, however, Rule 702 does not impose such a high standard for admissibility. In many cases, moreover, such "gold standard" evidence is not available. Epidemiological studies are difficult to design, expensive to conduct, and often take years to produce results. Many plaintiffs cannot wait to sue until such studies

are conducted. In the case of rare diseases affecting small numbers of people, epidemiological studies may not even be feasible. Requiring epidemiological evidence thus not only violates Rule 702, but also effectively makes it impossible for many toxic tort victims to seek recovery for their injuries.

The perverse consequences of the Eleventh Circuit's test are illustrated starkly by this case. To prove causation, petitioners offered the testimony of world-renowned experts that ingestion of large quantities of zinc contained in Procter & Gamble's ("P&G") Fixodent-brand denture cream can cause a serious neurological and hematological disorder known as "copper-deficiency myelopathy" or CDM. That opinion is well-accepted in the scientific community. The National Institutes of Health ("NIH") has issued a warning to that effect. The leading neurology textbook, published by Harvard Medical School, teaches medical students the same thing. Such widely accepted opinions clearly are not the type of "junk science" Rule 702 permits to be excluded. The Eleventh Circuit's jurisprudence on expert admissibility has gone far beyond the bounds authorized by this Court, and it warrants review.

The standard for admissibility of expert causation opinions in tort cases is a matter of national importance. Toxic tort cases continue to comprise a significant proportion of the federal judiciary's docket. Rule 702 is frequently outcome-determinative, because plaintiffs whose expert evidence on causation is excluded often cannot survive summary judgment. This Court should grant certiorari to resolve the divisions in the lower courts on this vital issue and correct the Eleventh Circuit's overly restrictive admissibility standard.

OPINIONS BELOW

The opinion of the court of appeals (App. 1a-37a) is reported at 766 F.3d 1296. The district court's order granting respondents' motion for summary judgment (App. 38a-49a) is unreported (but is available at 2012 WL 5407868).

JURISDICTION

The court of appeals entered its judgment on September 11, 2014. On December 3, 2014, Justice Thomas extended the time for filing a petition for a writ of certiorari to and including February 6, 2015. App. 53a. The jurisdiction of this Court is invoked under 28 U.S.C. § 1254(1).

RELEVANT RULE

Rule 702 of the Federal Rules of Evidence is reprinted at App. 52a.

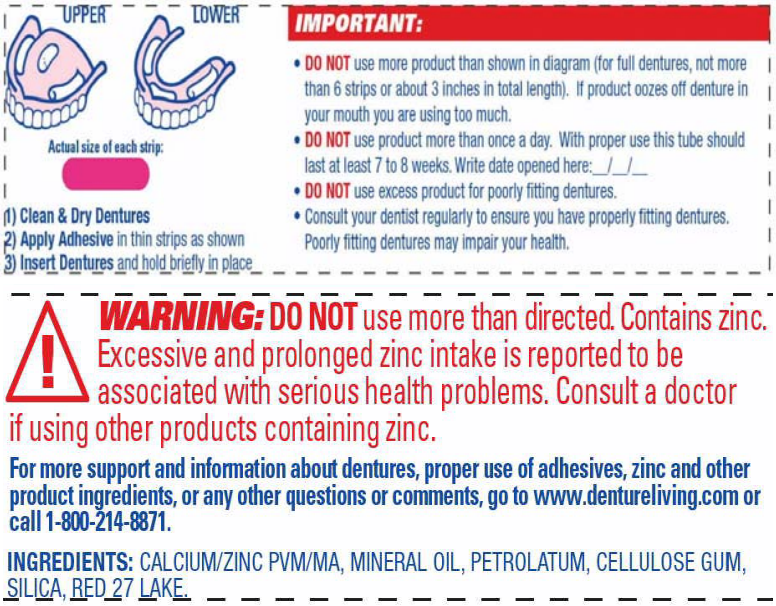
STATEMENT

1. In 2001, Marianne Chapman lost her teeth due to physical trauma and started wearing dentures. Between 2001 and 2008, following the directions on the label, Ms. Chapman used two to four tubes of Fixodent-brand denture cream per week. App. 1a-2a. Fixodent contains 17 mg of zinc per gram of denture cream, and a standard tube of Fixodent contains 68 grams of denture cream. Ms. Chapman's daily dosage of Fixodent contained more than 10 times the upper limit ("UL") of 40 mg/day prescribed by the Institute of Medicine at the National Academy of Sciences ("IOM"). *See* IOM, *Dietary Reference Intakes for Vitamin A, Vitamin K, Arsenic, Boron, Chromium, Copper, Iodine, Iron, Manganese, Molybdenum, Nickel, Silicon, Vanadium, and Zinc* 486 (2001) ("*IOM Reference Intakes*").

By 2006, Ms. Chapman had developed debilitating neurological symptoms, including difficulty walking ("gait ataxia"), numbness in her extremities, and severe pain in her hands and feet. She soon lost the use of her right hand and fingers, a condition known as "subacute bilateral asymmetric wrist and finger drop." App. 2a n.1. She also developed hematological problems, including anemia and neutropenia (low red and white blood cell counts, respectively). *Id.* Thereafter, Ms. Chapman was diagnosed definitively with CDM. As described by the leading neurology textbook: CDM is "a metabolic disease of the spinal cord caused by low copper, affecting the posterior and lateral columns . . . . Imbalance is the most common presenting complaint." Allan H. Ropper & Martin A. Samuels, *Adams and Victor's Principles of Neurology* 1215 (9th ed. 2009) ("*Adams and Victor's*").

2. Until late 2009, P&G did not warn consumers that Fixodent was formulated with high levels of zinc. Nor did P&G warn consumers that they should limit their use of Fixodent. To the contrary, it instructed them to "[u]se more if you need more hold."

Not until late 2009 did P&G finally change Fixodent's label to include "black box" warnings disclosing the presence of zinc and cautioning against excessive use:



In February 2011, the Food and Drug Administration ("FDA") notified P&G that it had "received numerous reports of adverse events related to the use of denture adhesives" and that "zinc contained in some denture adhesives may be a contributing factor in these adverse events." FDA, Notice and Recommended Action at 1 (Feb. 23, 2011), *available at* http://www.fda.gov/downloads/MedicalDevices/ResourcesforYou/Industry/UCM244652.pdf. The agency recommended that P&G "[r]eplac[e] zinc with an ingredient that presents less health risks in situations of overuse." *Id.* at 2. P&G has nonetheless refused to reformulate Fixodent. By contrast, GlaxoSmithKline eliminated zinc from its denture creams because of "the potential health risks associ-

ated with long-term excessive use of zinc-containing denture adhesives."[1]

3. In January 2009, prior to P&G's disclosure of Fixodent's high zinc content, Ms. Chapman became aware through her doctors of the possible connection between denture cream and zinc poisoning.[2] After blood tests revealed zinc poisoning, Ms. Chapman discontinued using Fixodent on January 28, 2009. Within two months, her balance began to improve. Her zinc blood level returned to normal within two weeks and, without receiving copper supplementation, her copper level was normal within a few months. The numbness and weakness in her hands, however, is irreversible.

4. On April 1, 2009, Ms. Chapman and her husband, Daniel Chapman, filed suit against P&G in Florida state court. App. 3a. P&G removed the case to federal court in the Southern District of Florida on diversity grounds. *Id.* Ms. Chapman's case was then consolidated for pre-trial proceedings with nearly 225 other similar cases by order of the Judicial Panel on Multidistrict Litigation.

---

[1] GlaxoSmithKline Press Release, *GSK Consumer Healthcare Warns Consumers of Potential Health Risks Associated with Long-Term Excessive Use of Zinc-Containing Denture Adhesives* (Feb. 18, 2010), *available at* http://us.gsk.com/en-us/media/press-releases/2010/gsk-consumer-healthcare-warns-consumers-of-potential-health-risks-associated-with-long-term-excessive-use-of-zinc-containing-denture-adhesives/.

[2] Although P&G did not disclose that Fixodent contained high zinc levels until late 2009, a 2008 study linking zinc in denture cream to neurologic disease led some physicians to investigate whether patients with similar symptoms were denture wearers. *See* S.P. Nations et al., *Denture Cream: An Unusual Source of Excess Zinc, Leading to Hypocupremia and Neurologic Disease*, 71 Neurology 639 (2008).

To demonstrate that Ms. Chapman's condition was caused by Fixodent, petitioners proffered five principal expert reports. Petitioners offered the testimony of four of those experts – Dr. George J. Brewer, Dr. Joseph R. Landolph, Dr. Ebbing Lautenbach, and Dr. Joseph Prohaska – to prove that Fixodent is capable of causing CDM (known as "general causation") while the fifth expert – Dr. Steven A. Greenberg – opined that Fixodent caused Ms. Chapman's CDM (known as "specific causation"). *See* Restatement (Third) of Torts: Liability for Physical and Emotional Harm § 28 cmt. c(3), at 405 (2010) ("Restatement") ("'General causation' exists when a substance is capable of causing a disease."); *id.* cmt. c(4), at 407 ("'Specific causation' exists when exposure to an agent caused a particular plaintiff's disease.").

a. Dr. Brewer is a Professor Emeritus of Genetics and Internal Medicine at the University of Michigan Medical School and was recognized even by P&G's experts as the world's foremost specialist on zinc and copper metabolism. Dr. Brewer opined that zinc in Fixodent can cause copper deficiency. That opinion rested on his path-breaking, FDA-approved dose-response experiments to determine whether zinc supplementation could be used to treat patients with Wilson's disease – an illness characterized by abnormally high copper levels. Dr. Brewer published the peer-reviewed results of his studies in a series of eight articles. *See* Expert Witness Report of George J. Brewer, M.D. at 6 & n.5 (dated Jan. 24, 2011) (D. Ct. Dkt. 1046-1). In 1997, based on Dr. Brewer's studies, the FDA approved the administration of three 25 mg doses of zinc acetate daily for the treatment of Wilson's disease. *See id.* at 5-6. Numerous independent, peer-reviewed studies subsequently

corroborated Dr. Brewer's work. *See IOM Reference Intakes* at 484-85, tbl. 12-7.

Dr. Brewer also explained that P&G's own internal studies – a pre-litigation dialysis study and a litigation-motivated pharmacokinetic study – demonstrated that, if Fixodent is ingested, the zinc in the denture cream becomes "dissociated" from the Fixodent polymer and active in the small intestine. Thus, Dr. Brewer concluded that zinc in Fixodent, if ingested, can cause copper deficiency.

Finally, Dr. Brewer explained that his opinion on causation was bolstered by a patient he treated in 1999. The patient had the hematological and neurological symptoms of zinc-induced CDM, but Dr. Brewer could not identify the source of the patient's excess zinc. When Dr. Brewer learned of the high levels of zinc contained in Fixodent, he went back and discovered that his patient had been using Fixodent several times daily for 18 years. When the patient discontinued using Fixodent, his blood tests normalized. Dr. Brewer thus concluded based on his medical judgment that the zinc in Fixodent caused the patient's CDM.

b. Dr. Landolph is a tenured Professor of Molecular Microbiology and Immunology and Pathology at the University of Southern California's Keck School of Medicine and a toxicologist with more than 40 years of experience and hundreds of peer-reviewed articles.

Dr. Landolph surveyed decades of peer-reviewed articles and scientific studies and concluded that it is "generally accepted in the scientific and medical communities" that excess zinc intake can cause CDM. Expert Witness Report of Joseph R. Landolph,

Jr., Ph.D. at 19 (dated Jan. 22, 2011) (D. Ct. Dkt. 1046-7).

Moreover, Dr. Landolph also explained the biological mechanisms by which zinc interferes with absorption of copper and thereby results in CDM. *See id.* at 19-20. Excessive zinc induces the body to produce more of a protein called metallothionein – a process called "upregulation." Because copper also binds to metallothionein, which is excreted from the body without entering the bloodstream, upregulation interferes with the body's ability to maintain healthy copper levels. Because copper plays a critical role in the structure and function of the nervous system, copper deficiency leads to a host of neurological problems classified as "myelopathies," a term that broadly refers to diseases affecting the spinal cord. Copper deficiency can also cause numerous hematological (or blood-related) problems, including anemia and neutropenia.

c. Dr. Lautenbach is a tenured Professor of Medicine and Epidemiology at the University of Pennsylvania with more than 120 peer-reviewed scientific articles. He has edited two epidemiology textbooks and peer-reviewed more than 20 scientific journals.

Dr. Lautenbach opined that the "numerous case reports . . . describing myeloneuropathy in patients using zinc containing denture adhesives" were sufficiently robust to generate a valid scientific conclusion that zinc in denture cream can cause CDM. Expert Witness Report of Ebbing Lautenbach, M.D., M.P.H., M.S.C.E. ¶ 45 (dated Mar. 24, 2011) ("Lautenbach Rep.") (D. Ct. Dkt. 1046-9). Dr. Lautenbach explained that epidemiologists have developed a widely accepted "Naranjo adverse drug reaction probability scale" to assess the likelihood that case reports indicate

that a particular drug caused an adverse event. *Id.* ¶ 43; *see* C.A. Naranjo et al., *A Method for Estimating the Probability of Adverse Drug Reactions*, 30 Clinical Pharmacology & Therapeutics 239 (Aug. 1981). "The Naranjo scoring method is an accepted pharmacoepidemiologic approach with well-recognized reliability and validity, that has been used extensively in the medical literature to assess causality in case reports and case series." Expert Witness Report of Ebbing Lautenbach, M.D., M.P.H., M.S.C.E. ¶ 45 (dated Apr. 30, 2012) (D. Ct. Dkt. 2205-7).

Applying the Naranjo scale, Dr. Lautenbach concluded that the numerous published case reports linking CDM to denture adhesives provide a "most compelling" basis for concluding that denture adhesives are a "probable" cause of CDM. Lautenbach Rep. ¶ 45. Specifically, he noted that, "[i]n a large subset of these reports, elevated zinc levels were demonstrated as well as copper deficiency." *Id.* Moreover, "[p]erhaps most compelling, in a number of these patients, signs and symptoms as well as laboratory abnormalities improved or resolved following cessation of denture adhesive use." *Id.*

Finally, Dr. Lautenbach noted that the dramatic increase in adverse-event reports linking Fixodent to CDM, which the FDA recognized in its notice to P&G, corroborated the causal link between zinc in denture cream and CDM. *Id.* ¶ 40.

d. Dr. Prohaska is a biochemistry and molecular biology Professor at the University of Minnesota Medical School. Dr. Prohaska explained the biological processes by which copper deficiency causes the hematological symptoms (anemia and neutropenia) from which Ms. Chapman suffered. Dr. Prohaska

also testified, consistent with Dr. Landolph, that upregulation of metallothionein resulting from excess zinc intake could cause copper deficiency. As discussed below, Dr. Prohaska's opinion was not challenged under Rule 702.

e. Dr. Greenberg is a Professor of Neurology at Harvard Medical School and a specialist in neuromuscular disease at the Brigham and Women's Hospital with extensive clinical experience.

Dr. Greenberg based his "specific causation" opinion that the zinc in Fixodent caused Ms. Chapman's CDM on a differential etiology (also known as "differential diagnosis") of Ms. Chapman. First, Dr. Greenberg noted that, in addition to zinc-induced CDM, vitamin B12 deficiency is the only other disease that could account for the precise combination of neurological and hematological symptoms experienced by Ms. Chapman. He thus ruled out other potential causes inconsistent with those symptoms.

Dr. Greenberg also ruled out B12 deficiency because Ms. Chapman "experienced relentless neurological deterioration despite well-documented adequate B12 treatment," and her blood tests showed normal B12 levels during the relevant period. Expert Witness Report of Steven A. Greenberg, M.D., M.S. at 9-10 (dated Jan. 23, 2011) (D. Ct. Dkt. 1046-6). Thus, he concluded that the only remaining plausible cause of Ms. Chapman's illness was zinc-induced CDM. After ruling out alternative causes of Ms. Chapman's elevated zinc levels, Dr. Greenberg concluded that the zinc in Fixodent caused Ms. Chapman's CDM. *See id.* at 8-9.

5. On P&G's motion, the district court excluded the opinions of Drs. Brewer, Landolph, Lautenbach, and Greenberg (but not Dr. Prohaska) as unreliable

under Federal Rule of Evidence 702.[3] First, after surveying "Eleventh Circuit *Daubert* jurisprudence in toxic-tort cases," the court excluded the experts' opinions because they lacked five elements the court concluded were essential to demonstrate causation under circuit law: "the dose-response relationship, epidemiological studies, the amount of background risk of the disease, an understanding of the physiological mechanisms involved, and clinical studies or tests." *In re Denture Cream Prods. Liab. Litig.*, 795 F. Supp. 2d 1345, 1351 (S.D. Fla. 2011).

The district court first noted that petitioners could not identify the exact dose-response relationship between Fixodent and CDM.[4] Although Dr. Brewer's Wilson's disease experiments determined the dose-response between zinc acetate and decreased serum copper levels, the court held that this was not sufficient to demonstrate a dose-response relationship between Fixodent and CDM. *See id.* at 1353 ("[T]here is no dose-response evidence which Plaintiffs' experts may use to reliably infer what type of exposure level to Fixodent is necessary to induce a negative copper balance, to cause a copper deficiency, or to cause a myelopathy.").

The district court next concluded that "Plaintiffs' experts have no analytical epidemiological evidence on which to base their inference of causation."

---

[3] No challenge was made to the qualifications of any of petitioners' experts.

[4] A "dose-response relationship" ordinarily "means that the greater the exposure, the greater the risk of disease." Michael D. Green, D. Michal Freedman & Leon Gordis, *Reference Guide on Epidemiology* ("Green, *Reference Guide*"), *in* Federal Jud. Ctr. & Nat'l Research Council, *Reference Manual on Scientific Evidence* 549, 603 (3d ed. 2011) ("*Reference Manual*").

Id. at 1354.[5] Although the court recognized Dr. Lautenbach's opinion that the descriptive epidemiological evidence in the form of case reports was sufficiently reliable to infer causation, it disagreed with his conclusion, "because the case studies Plaintiffs' experts rely on suffer from a number of inaccuracies and methodological weaknesses that undermine their evidentiary value." *Id.* The court also found that petitioners' experts lacked knowledge of the background risk of CDM in the general population. *Id.* at 1355-56.[6]

The district court concluded that petitioners had presented some evidence as to the physiological mechanisms linking excessive zinc intake and CDM, as well as some clinical trial evidence (namely, Dr. Brewer's Wilson's disease experiments and P&G's pharmacokinetic studies). But the court concluded that this evidence did not satisfy the Eleventh Circuit's evidentiary requirements because they were not "dispositive of the ultimate question of whether Fixodent can cause copper-deficiency myelopathy." *Id.* at 1357; *see also id.* at 1356 (stating that evidence of physiological mechanisms was lacking because the mechanism by which copper deficiency leads to

---

[5] Analytical epidemiological evidence refers to large-scale experimental or observational studies comparing individuals exposed to the suspected toxin with individuals who have not been exposed to determine whether there is a statistically significant association between the toxin and disease. *See* Green, *Reference Guide* at 555-56.

[6] In epidemiology, background risk refers to the incidence of a disease in the general population. Epidemiologists compare the risk of disease among those who have been exposed to the background risk in the unexposed population in order to calculate the "relative risk" associated with exposure. *See* Green, *Reference Guide* at 566-67.

neurological disease "remains uncertain") (internal quotation marks omitted).

In sum, the district court stated: "Th[e] [causal link between Fixodent and CDM] is not ridiculous, but neither is it necessarily true." *Id.* at 1367. Because petitioners' experts could not present evidence that "guarantee[d] [their] conclusion is true," *id.* at 1358, the court determined that their testimony was inadmissible.

After excluding the Chapmans' causation experts, the district court proceeded to grant summary judgment to P&G.[7] In doing so, the court rejected the Chapmans' arguments that they could prove that Fixodent can cause CDM through (1) Dr. Prohaska, whose testimony P&G had not sought to exclude; (2) the testimony of P&G's own experts that linked Fixodent to CDM; and (3) the testimony of Ms. Chapman's treating physicians. *See* App. 43a-49a.

6. The Eleventh Circuit affirmed the district court's exclusion of petitioners' general causation experts under Rule 702. The appeals court's reasoning differed from that of the district court. The appeals court identified three forms of evidence, in contrast to the five identified by the district court, that "this circuit has recognized as indispensable to proving the effect of an ingested substance." App. 18a.

---

[7] Initially, at the district court's suggestion, the parties stipulated to the entry of summary judgment so that petitioners could appeal the exclusion of their expert causation evidence. The Eleventh Circuit dismissed that appeal for lack of jurisdiction, holding that the parties' stipulation eliminated any "case or controversy" under Article III. After remand, the district court vacated the stipulated summary judgment under Federal Rule of Civil Procedure 60(b). P&G then filed a motion for summary judgment, which petitioners opposed. *See* App. 4a-7a, 41a-43a (describing procedural history).

First, the court faulted petitioners' experts for not being able to demonstrate a dose-response relationship between Fixodent and CDM. *See* App. 15a-17a. The court located this requirement in its prior decision in *McClain v. Metabolife International, Inc.*, 401 F.3d 1233 (11th Cir. 2005), which stated that the dose-response relationship "is the single most important factor to consider in evaluating whether an alleged exposure caused a specific adverse effect." *Id.* at 1239, 1242 (internal quotation marks omitted). The Eleventh Circuit found this element lacking because petitioners' experts could not provide, at each step of the causal chain, the precise dosage required to increase the individual's risk of disease. *See* App. 16a ("[N]either the Chapmans' general-causation experts 'nor the articles on which they rely determine how much Fixodent must be used for how long to increase the risk of a copper-deficiency, or for how long a copper-deficiency must persist before an individual is at an increased risk of developing a myelopathy.'") (quoting *Denture Cream Prods. Liab. Litig.*, 795 F. Supp. 2d at 1352).

Second, the court held that petitioners' experts had "'no analytical epidemiological evidence on which to base their inference of causation.'" App. 17a (quoting *Denture Cream Prods. Liab. Litig.*, 795 F. Supp. 2d at 1354). Citing its prior decision in *Kilpatrick v. Breg, Inc.*, 613 F.3d 1329, 1337 n.8 (11th Cir. 2010), the court deemed such evidence essential to a reliable opinion on general causation.

Third, again citing *McClain*, the court held that it was a "'serious methodological deficiency'" that "the Chapmans' 'causation experts uniformly testified that they did not know the background risk of copper-deficiency myelopathy'" in the population as a whole. App. 17a (quoting *Denture Cream Prods.*

Liab. Litig., 795 F. Supp. 2d at 1355, and citing *McClain*, 401 F.3d at 1243).

The court of appeals did not assess the reliability of the scientific evidence on which petitioners' experts did base their opinions. Rather, according to the court below, the Chapmans' inability to supply these three pieces of "indispensable" evidence made the remaining scientific bases for their opinions insufficient as a matter of law. As the court stated:

> Given the deposition admissions of Dr. Brewer, Dr. Lautenbach, and Dr. Landolph regarding their lack of knowledge of dose-response, epidemiological evidence, and background risk of disease, methodologies this circuit has recognized as indispensable to proving the effect of an ingested substance, we conclude that the testimonies of these proffered experts could not establish general causation of myelopathy by Fixodent. Because these experts have failed to demonstrate the primary methods for proving the zinc in Fixodent causes myelopathy, their secondary methodologies, including plausible explanations, generalized case reports, hypotheses, and animal studies are insufficient proof of general causation.

App. 18a-19a.

As to Dr. Greenberg's specific-causation opinion, the court of appeals affirmed the district court's holding that his differential diagnosis was inadmissible because the Chapmans lacked reliable evidence of a general causal link between Fixodent and CDM. *See* App. 25a ("The district judge determined 'Dr. Greenberg's differential diagnosis is not reliable as a matter of law in the Eleventh Circuit because he ruled-in and considered an etiology – Fixodent-induced copper-deficiency myelopathy – that has not

been established to cause Ms. Chapman's disease.'") (quoting *Denture Cream Prods. Liab. Litig.*, 795 F. Supp. 2d at 1366). The court of appeals also echoed some of the district court's criticisms of Dr. Greenberg for having failed to consider and rule out certain other potential causes of Ms. Chapman's symptoms. *See* App. 24a-25a. However, the appeals court did not indicate that those criticisms alone would have been sufficient to affirm the district court's exclusion of Dr. Greenberg's testimony. *See* App. 25a.[8]

The court of appeals also proceeded to affirm the district court's summary judgment ruling. The court agreed that petitioners could not prove causation through the testimony of Dr. Prohaska, because his expertise "is hematology and not myelopathy at issue in this case." App. 32a. The court also affirmed the district court's refusal to permit the Chapmans to prove causation through P&G's own experts, concluding that they, too, had "'not been vetted for reliability.'" App. 34a (quoting district court at App. 48a).[9]

---

[8] The court of appeals also affirmed the exclusion of the testimony of two other general causation experts, Dr. Michael Wogalter and Dr. J. Anthony von Fraunhofer, "whose testimonies were premised on the toxicity of Fixodent." App. 25a.

[9] Petitioners did not appeal the district court's ruling that the testimony of Ms. Chapman's treating physicians was insufficient, by itself, to create a triable issue of fact on causation.

REASONS FOR GRANTING THE PETITION

I. THE DECISION BELOW DEEPENS A 5-2 CIRCUIT SPLIT ON WHETHER EXPERT OPINIONS ON GENERAL CAUSATION MUST BE SUPPORTED BY EPIDEMIOLOGICAL EVIDENCE

A. The Decision Below Is At Odds With The Standard For Admissibility In The First, Third, Fourth, Ninth, And D.C. Circuits

The decision below conflicts with the standard that the First, Third, Fourth, Ninth, and D.C. Circuits have adopted for evaluating the admissibility of expert testimony on general causation. Contrary to the decision below, the rule in those five circuits is that the absence of epidemiological evidence is not a valid ground to exclude a properly qualified medical expert's opinion that a toxic agent can cause a particular disease. To the extent those courts have excluded general causation opinions that were not based on epidemiological evidence, they have done so expressly because that testimony contradicted available epidemiological studies negating a causal relationship. Where, as here, there has been no epidemiological study of the toxic substance in question, the unavailability of such evidence is not dispositive.

First Circuit. In *Milward v. Acuity Specialty Products Group, Inc.*, 639 F.3d 11 (1st Cir. 2011), the First Circuit squarely rejected a requirement that causation experts rely on epidemiological evidence. In that case, the plaintiff sought to introduce the opinion of a toxicologist that benzene contained in certain workplace products could cause a rare type of blood cancer known as acute promyelocytic leukemia, or "APL." Employing a "'weight of the evidence' approach to making causal determinations," the expert

opined that there was sufficient evidence of general causation even though there was a "lack of statistically significant epidemiological evidence." *Id.* at 17, 24. The district court excluded the opinion, stating that the lack of statistically significant epidemiological evidence made his causation opinion merely conjectural.

The First Circuit reversed, stating that "[e]pidemiological studies are not per se required as a condition of admissibility." *Id.* at 24. "[T]his is not a situation in which the available epidemiological studies found that there is no causal link," the court emphasized. *Id.* "Rather, this is a case in which there is a lack of statistically significant epidemiological evidence, and in which the rarity of APL and difficulties of data collection in the United States make it very difficult to perform epidemiological study of the causes of APL that would yield statistically significant results." *Id.* "Under these circumstances," the court held, "the [district] court erred in holding that [the expert's] attempt to support his conclusion with data that concededly lacks statistical significance was a deviation from sound practice of the scientific method." *Id.* at 25 (internal quotation marks omitted).

Third Circuit. In *In re Paoli Railroad Yard PCB Litigation*, 35 F.3d 717 (3d Cir. 1994), the Third Circuit reversed the district court's exclusion of an expert's causation opinion based on toxicological rather than epidemiological evidence (namely, animal studies), noting that such studies should not be deemed unreliable "where the epidemiological data is inconclusive." *Id.* at 781. The court noted that "[i]n the absence of epidemiologic proof in humans we must drop to our second tier in the understanding of human carcinogenic prediction: Animal testing." *Id.* at 780 (internal quotation marks omitted). Like the

First Circuit in *Milward*, the court contrasted those cases where "significant epidemiological data contradicted the animal studies." *Id.* at 779.

Similarly, in *Heller v. Shaw Industries, Inc.*, 167 F.3d 146 (3d Cir. 1999), the Third Circuit affirmed the admission of expert testimony by a board-certified physician that the plaintiffs' respiratory problems were caused by volatile organic compounds ("VOCs") emitted from carpeting manufactured by the defendant. The defendant sought to exclude the expert's opinion on the ground that he could cite no published studies demonstrating that VOCs could cause respiratory ailments. The court of appeals rejected that argument: "Given the liberal thrust of the Federal Rules of Evidence, the flexible nature of the *Daubert* inquiry, and the proper roles of the judge and the jury in evaluating the ultimate credibility of an expert's opinion, we do not believe that a medical expert must always cite published studies on general causation in order to reliably conclude that a particular object caused a particular illness." *Id.* at 155. "To so hold would doom from the outset all cases in which the state of research on the scientific ailment or on the alleged causal agent was in its early stages." *Id.*

Fourth Circuit. The Fourth Circuit has likewise rejected a requirement that causation experts base their opinions on epidemiological evidence. In *Benedi v. McNeil-P.P.C., Inc.*, 66 F.3d 1378 (4th Cir. 1995), the court affirmed the district court's denial of the defendant's motion to exclude the plaintiff's expert opinion that Extra-Strength Tylenol, in combination with alcohol, could cause liver damage. Benedi's treating physicians rendered their opinions based on the plaintiff's medical history, a physical examination, lab and pathology data, and peer-

reviewed literature. *See id.* at 1384. The defendant, McNeil, "contend[ed] that because Benedi's experts did not rely upon epidemiological data in formulating their opinions, their testimony is inadmissible under *Daubert*." *Id.* The court rejected that argument as inconsistent with *Daubert*. *See id.* The court reasoned that requiring epidemiological evidence would be unfair to victims of previously unknown toxins: a "defendant should not be allowed 'to escape liability simply because . . . there are, as yet, no epidemiological studies concerning the health risks associated with [the toxic substance].'" *Id.* (quoting *City of Greenville v. W.R. Grace & Co.*, 827 F.2d 975, 980 n.2 (4th Cir. 1987)); *see also Westberry v. Gislaved Gummi AB*, 178 F.3d 257, 262-63 (4th Cir. 1999) (holding that a reliable differential diagnosis alone may provide a valid foundation for a general causation opinion, even when no epidemiological studies are available).

Ninth Circuit. Similarly, the Ninth Circuit reversed summary judgment predicated on the exclusion of the plaintiffs' causation experts in *Kennedy v. Collagen Corp.*, 161 F.3d 1226 (9th Cir. 1998). In doing so, the court rejected the district court's conclusion that the testimony was unreliable because it was unsupported by epidemiological studies. Noting that "[o]ther circuits . . . have found that it is scientifically permissible to reach a conclusion on causation without these types of studies," the court concluded that "[t]he fact that a cause-effect relationship . . . has not been conclusively established does not render [an expert's] testimony inadmissible." *Id.* at 1229-30 (citing *Benedi*, 66 F.3d at 1384, and the D.C. Circuit's decision in *Ambrosini*, discussed *infra* p. 23); *accord In re Berg Litig.*, 293 F.3d 1127, 1130 (9th Cir. 2002) ("Nor is epidemiological evidence the sole method of establishing causation.").

D.C. Circuit. Finally, the D.C. Circuit has held that an expert's inability to cite epidemiological evidence is not grounds for exclusion under Rule 702 where no epidemiological evidence is available. In *Ambrosini v. Labarraque*, 101 F.3d 129 (D.C. Cir. 1996), the D.C. Circuit reversed the exclusion of the plaintiffs' expert, who opined that the birth-control drug Depo-Provera caused the birth defects suffered by the plaintiffs' daughter. Like the court below in this case, the district court in *Ambrosini* excluded the testimony because the expert could point to no epidemiological studies that established "the relative risk between exposed and unexposed populations." *Id.* at 135 (internal quotation marks omitted). The court of appeals disagreed, holding that, "[e]ven where a party has admitted that no biochemical or epidemiological test has been done that can conclusively establish a link between a drug and an illness, [its] expert evidence on the subject is not rendered inadmissible." *Id.* at 138.

The *Ambrosini* court stressed that requiring epidemiological evidence as a precondition for admissibility is inappropriate where there has been limited opportunity for such testing. In that case, whether Depo-Provera caused birth defects had "not attracted significant scientific scrutiny" because the drug was no longer prescribed for pregnant women, consistent with FDA guidelines. *Id.* at 134. The court stressed that "'products liability law does not preclude recovery until a "statistically significant" number of people have been injured.'" *Id.* at 138 (quoting *Ferebee v. Chevron Chem. Co.*, 736 F.2d 1529, 1536 (D.C. Cir. 1984)); *see also Mendes-Silva v. United States*, 980 F.2d 1482, 1487 (D.C. Cir. 1993) (holding that the absence of epidemiological evidence is not grounds for exclusion where "no conclusive epidemiological studies exist[ed]").

The D.C. Circuit reaffirmed *Ambrosini* in *Raynor v. Merrell Pharmaceuticals Inc.*, 104 F.3d 1371 (D.C. Cir. 1997). The court distinguished *Ambrosini* because, unlike Depo-Provera, the drug in *Ambrosini*, Bendectin had been "extensively studied and a wealth of published epidemiological data ha[s] been amassed, none of which has concluded that the drug is teratogenic." *Id.* at 1374 (internal quotation marks omitted); *see Meister v. Medical Eng'g Corp.*, 267 F.3d 1123, 1130 (D.C. Cir. 2001) (affirming exclusion of plaintiffs' causation experts as contrary to available epidemiological evidence). These cases thus establish that, where no epidemiological evidence is available, an expert's inability to cite such evidence is not valid grounds for exclusion under Rule 702. By contrast, where epidemiological studies have been conducted and show no statistically significant association, an expert's opinion of causation based solely on non-epidemiological evidence may not be reliable.

Had petitioners' case been brought in the First, Third, Fourth, Ninth, or D.C. Circuit, the district court's exclusion of their general causation experts would have been reversible error. The inability of those experts to support their conclusions with epidemiological evidence would not have been dispositive because this is a case in which epidemiological studies have not been conducted on the drug in question, not a case where the epidemiological studies that have been conducted show no causation. *See also* Restatement § 28 reporters' note cmt. c(3), at 443 ("Many courts find that requiring proof by scientific evidence that does not exist and is not reasonably available to the plaintiff when other, reasonably probative evidence exists is an overbroad method for

screening cases.").[10] Indeed, this case brings that key distinction into stark relief, because the principal reason why Fixodent was never subjected to epidemiological analysis is that, for more than two decades, P&G concealed the fact that Fixodent was formulated with high concentrations of zinc.

---

[10] The Tenth Circuit has also held, albeit in *dicta*, that, "[i]n cases where there is no epidemiology challenging causation available, epidemiological evidence would not necessarily be required" for admissibility under Rule 702. *Norris v. Baxter Healthcare Corp.*, 397 F.3d 878, 882 (10th Cir. 2005). The court affirmed the district court's exclusion of the plaintiffs' experts in that case, however, because the methodology on which they relied – case reports and differential diagnosis – could not reliably overcome the weight of epidemiological evidence finding no causal link between silicone breast implants and disease. *See id.* (stating that, where there are epidemiological studies "demonstrating the absence of a causal relationship," "it is necessary to at least address it with evidence that is based on medically reliable and scientifically valid methodology"); *accord Hollander v. Sandoz Pharms. Corp.*, 289 F.3d 1193, 1211-12 (10th Cir. 2002).

The Second Circuit also cited the difficulty of obtaining such evidence as a factor in affirming the admission of expert opinion that exposure to extremely high doses of the prescription endometriosis drug Danocrine could cause primary pulmonary hypertension ("PPH"). *See Zuchowicz v. United States*, 140 F.3d 381, 385 (2d Cir. 1998) ("The rarity of PPH, combined with the fact that so few human beings have ever received such a high dose of Danocrine, obviously impacted on the manner in which the plaintiff could prove causation. The number of persons who received this type of overdose was simply too small for the plaintiff to be able to provide epidemiological, or even anecdotal, evidence linking PPH to Danocrine overdoses.").

B. The Decision Below Is Consistent With The Fifth Circuit's Admissibility Standard

Unlike the First, Third, Fourth, Ninth, and D.C. Circuits, the Fifth Circuit has embraced a rule requiring epidemiological evidence as a prerequisite to the admissibility of an expert's general causation opinion. That rule originated in *Brock v. Merrell Dow Pharmaceuticals, Inc.*, 874 F.2d 307, *modified on reh'g*, 884 F.2d 166 (5th Cir. 1989) (per curiam), in which the court held that the plaintiffs' "failure to present statistically significant epidemiological proof that Bendectin causes limb reduction defects to be fatal to their case." 884 F.2d at 167. As commentators have noted, *Brock* was "[t]he first case to employ an epidemiologic threshold for proof of agent-disease causation." Restatement § 28 reporters' note cmt. c(3), at 442.

Since *Brock*, the Fifth Circuit has reaffirmed that threshold requirement. In *Christophersen v. Allied-Signal Corp.*, 902 F.2d 362 (5th Cir. 1990), the panel sought to retreat from *Brock* and re-align the circuit's case law with that of other circuits. *Id.* at 367 (stating that *Brock* "specifically declined to hold that 'epidemiologic proof is a necessary element in all toxic tort cases'") (quoting *Brock*, 874 F.2d at 313). The Fifth Circuit granted rehearing *en banc*, reversed the panel's decision, and held that the expert's methodology was unreliable because it was not based on epidemiological methods. *See Christophersen v. Allied-Signal Corp.*, 939 F.2d 1106, 1115-16 (5th Cir. 1991) (per curiam) (en banc); *see also id.* at 1128 n.19 (Reavley, J., dissenting) (describing the *en banc* majority as creating a "rigid alliance between law and epidemiology" that "creates virtually insurmountable obstacles to claimants suffering from rare or new diseases").

The Fifth Circuit now routinely excludes general causation expert opinions on the ground that they are not supported by statistically significant epidemiological studies. *See*, *e.g.*, *Allen v. Pennsylvania Eng'g Corp.*, 102 F.3d 194, 197 (5th Cir. 1996) ("While appellants' experts acknowledge the lack of statistically significant epidemiological evidence, they rely on certain studies as 'suggestive' of a link between [exposure to the toxic agent] and brain cancer. 'Suggestiveness' is not by the experts' own admission statistical significance . . . ."); *Burleson v. Texas Dep't of Criminal Justice*, 393 F.3d 577, 586 (5th Cir. 2004) ("Here, as in *Allen*, there are no epidemiological studies supporting a correlation between the suggested causative agent and the type of cancer experienced by the plaintiff."); *Wells v. SmithKline Beecham Corp.*, 601 F.3d 375, 380 (5th Cir. 2010) (while non-epidemiological evidence is "not per se inadmissible evidence on general causation, this court has frowned on causative conclusions bereft of statistically significant epidemiological support") (internal quotation marks and footnote omitted).

The decision below thus deepens the existing division between the Fifth Circuit and the First, Third, Fourth, Tenth, and D.C. Circuits on the necessity of epidemiological evidence for the admissibility of general causation expert opinions. *See* Restatement § 28 reporters' note cmt. c(3), at 443 (noting that "[a] quite substantial body of case law and commentary rejects" the Fifth Circuit's threshold test); *see also Moore v. Ashland Chem. Inc.*, 151 F.3d 269, 282-83 (5th Cir. 1998) (en banc) (Dennis, J., dissenting) (noting that the Fifth Circuit's standard conflicts with the D.C. Circuit's decision in *Ambrosini*, the Fourth Circuit's decision in *Benedi*, and the Third Circuit's decision in *Paoli*). This Court should grant certiorari to resolve this clear division among the circuit courts.

II. THE ELEVENTH CIRCUIT'S REQUIREMENT OF EPIDEMIOLOGICAL EVIDENCE IS INCONSISTENT WITH *DAUBERT* AND ITS PROGENY

The Eleventh Circuit's holding that epidemiological evidence is "indispensable" to support a general causation opinion in toxic tort cases is contrary to this Court's precedents interpreting Rule 702. Indeed, the lower courts' exclusion of expert opinions that are consistent with conclusions published in Harvard Medical School textbooks and by the NIH illustrates how far the Eleventh Circuit's admissibility standard has deviated from Rule 702's mandate.

A. The Eleventh Circuit's Stringent Admissibility Requirement Exceeds Courts' Limited Gatekeeping Role Under Rule 702

The core purpose of Rule 702 was to expand the scope of admissible expert testimony. *See Daubert*, 509 U.S. at 588 (describing the "liberal thrust" of the Federal Rules); *id.* at 589 (discussing "the Rules' permissive backdrop"). As this Court's cases make clear, it is not the role of federal district judges to resolve scientific disagreements among experts. That is the jury's province. *See Kumho Tire Co. v. Carmichael*, 526 U.S. 137, 153 (1999) ("the jury must decide among the conflicting views of different experts"). Courts may not limit the jury's ability to consider expert opinions unless they are "junk science" that do not even qualify as "'scientific . . . knowledge.'" *Daubert*, 509 U.S. at 589-90 (quoting Rule 702).

The Eleventh Circuit's requirement of epidemiological evidence reverses the "liberal thrust" of the Federal Rules and exceeds the "gatekeeping" function of the courts by demanding an unduly high degree of scientific certainty as a precondition for

admissibility. Requiring that all general causation be supported be epidemiological evidence effectively requires plaintiffs to prove causation at the admissibility stage. But the standard for admissibility is not whether the expert's opinions are correct; the standard is whether the expert has a reasonable scientific basis for his opinion. *See id.* at 590 (standard is whether the expert has "'good grounds,' based on what is known").

Indeed, requiring that all expert opinions on general causation be supported by epidemiological evidence effectively revives the "uncompromising 'general acceptance' test" of *Frye v. United States*, 293 F. 1013 (D.C. Cir. 1923), which *Daubert* held superseded by Rule 702, 509 U.S. at 596. The district court in *Daubert* had applied *Frye* in ruling that "expert opinion which is not based on epidemiological evidence is not admissible to establish causation." *Id.* at 583-84. This Court vacated the Ninth Circuit's affirmance of that decision and made clear that artificial bright-line rules and definitive "checklist[s]" are inconsistent with Rule 702's more permissive standard for admissibility. *Id.* at 593.

As this Court made clear in *Daubert*, the limited gatekeeping function of the courts does not mean that debatable scientific opinions will go unscrutinized. Rather, *Daubert* and Rule 702 reflect confidence that debates between experts are better resolved by juries after they have been subjected to "[v]igorous cross-examination, presentation of contrary evidence, and careful instruction on the burden of proof." *Id.* at 596. The Eleventh Circuit's overly restrictive admissibility standard thus impairs the truth-seeking function of the judicial system by short-circuiting the adversarial process.

B. The Eleventh Circuit's Rule Undermines The Policies Underlying Rule 702

This case well illustrates how the Eleventh Circuit's admissibility standard undermines Rule 702's policies. As this Court made clear in *Kumho Tire*, the core purpose of Rule 702 is to ensure that experts in the courtroom have applied "the same level of intellectual rigor that characterizes the practice of an expert in the relevant field." 526 U.S. at 152. The Eleventh Circuit's rule, however, imposes a far higher standard of scientific certainty than the medical community itself requires. "In the actual practice of medicine, physicians do not wait for conclusive, or even published and peer-reviewed, studies to make diagnoses to a reasonable degree of medical certainty." *Heller*, 167 F.3d at 155. Rather, medical experts reach conclusions about causation by looking at all the evidence available and "reasoning to the best explanation." *Milward*, 639 F.3d at 23 (describing the "weight of the evidence" methodology).

Here, the lower courts' conclusion that petitioners' experts were unreliable is directly contrary to the broad consensus in the scientific community that zinc in denture cream can cause CDM. The NIH views the scientific evidence as sufficient to conclude that "chronic, excessive use [of denture creams] can lead to zinc toxicity, resulting in copper deficiency and neurologic disease." NIH, Dietary Supplement Fact Sheets: Zinc – Health Professional, http://ods.od.nih.gov/factsheets/Zinc-HealthProfessional. Likewise, *Adams and Victor's*, the Harvard Medical School neurology textbook, teaches medical students that "[CDM] refers to a metabolic disease of the spinal cord caused by low copper . . . . Of importance in causation in some patients is excess zinc intake in

the form of health supplements, coin swallowing, and denture creams." *Adams and Victor's* at 1215.

Other leading neurology texts also teach that excess zinc can cause CDM. According to *Merritt's Neurology*, published by Columbia Medical School:

> Copper deficiency is extremely rare [and] may present as a myelopathy or myeloneuropathy . . . . These patients have gait difficulty, sensory ataxia, and spasticity, and may also have optic atrophy, mimicking subacute combined degeneration of vitamin B_{12} deficiency. Copper malabsorption can also result from excessive ingestion of zinc . . . .

Merritt's Neurology 1037 (Lewis P. Rowland & Timothy A. Pedley eds., 12th ed. 2010).

Scientific opinions that are published by Harvard Medical School and adopted by the NIH cannot possibly be so unreliable as to qualify as "junk science." Under this Court's precedents, those expert opinions should have been admitted under Rule 702 and considered by the jury at trial.

III. THIS CASE PRESENTS AN EXCELLENT VEHICLE FOR DECIDING AN ISSUE OF NATIONAL IMPORTANCE

A. Resolving The Correct Standard For Admissibility Of Expert Causation Opinions Is Critically Important To Toxic Tort Cases Nationwide

Causation in toxic tort cases is perhaps the single most prevalent issue on which courts must apply Rule 702's standard for the admissibility of expert opinions. *See*, *e.g.*, *Daubert*, 509 U.S. at 584 (causal relationship between Bendectin and birth defects); *General Elec. Co. v. Joiner*, 522 U.S. 136, 140-41 (1997) (causal relationship between PCBs and lung

cancer). The application of Rule 702 in such cases is usually outcome-determinative: litigants' success in mass tort actions is often determined by whether plaintiffs can present sufficiently reliable expert evidence of general causation to survive *Daubert* scrutiny and create a triable issue for a jury. *See* Edward K. Cheng, *Erie and the Rules of Evidence*, 65 Vand. L. Rev. En Banc 231, 231 n.2 (2012). The decision below thus creates a circuit conflict on a question that is of broad significance in the large number of toxic tort cases nationwide. *See* Deborah R. Hensler, *Has the Fat Lady Sung? The Future of Mass Torts*, 26 Rev. Litig. 883, 904-05 (2007) (finding that mass tort litigation is still "very much alive" and continues to comprise a significant proportion of the federal courts' docket).

Moreover, the Eleventh Circuit's decision warrants review because it creates an insuperable bar to recovery for many toxic tort victims. Epidemiological evidence is generally available only in the case of massive public health failures, and then only long after the fact. *See* Bernard D. Goldstein & Mary Sue Henifin, *Reference Guide on Toxicology*, *in Reference Manual* 633, 660 ("As a general rule, unequivocally positive epidemiological studies reflect prior work-place practices that led to relatively high levels of chemical exposure for a limited number of individuals and that, fortunately, in most cases no longer occur now."); Restatement § 28 cmt. c(3), at 407 ("Epidemiologic studies are expensive and can take considerable time to design, conduct, and publish. For disease processes with long latency periods, valid studies cannot be performed until the disease has manifested itself. As a consequence, some plaintiffs may be forced to litigate long before epidemiologic research is available.").

Requiring epidemiological evidence thus unfairly shuts the courthouse door to the victims of all but the most egregious, longstanding mass torts. As the Eighth Circuit stated in *Turner v. Iowa Fire Equipment Co.*, 229 F.3d 1202 (8th Cir. 2000), "[t]he first several victims of a new toxic tort should not be barred from having their day in court simply because the medical literature, which will eventually show the connection between the victims' condition and the toxic substance, has not yet been completed." *Id.* at 1208-09.

The decision below also will distort manufacturers' incentives to avoid the use of harmful substances. As this Court has recognized, state tort law generates important economic incentives to disclose safety risks and reduce or eliminate the manufacture of products containing dangerous substances. *See Wyeth v. Levine*, 555 U.S. 555, 579 (2009); *see also Joiner*, 522 U.S. at 148-49 (Breyer, J., concurring). Through its prohibitively high standard for expert testimony on causation, the decision below effectively immunizes manufacturers from liability for any toxic agent for which epidemiological evidence is not available, and thus dramatically reduces their incentive to ensure the safety of their products.

B. This Case Presents An Excellent Vehicle For Deciding The Question Presented

This case presents an unusually good vehicle for review by this Court. Although most evidentiary rulings are interlocutory, there is no doubt about the Court's jurisdiction in this case, as the decision below is an appeal from a grant of summary judgment.

Moreover, the Eleventh Circuit's exclusion of petitioners' general causation expert opinions was integral to its judgment below. Although the court of

appeals also referred to the district court's criticism of Dr. Greenberg's alleged failure to rule out certain other alternative causes for Ms. Chapman's symptoms, those criticisms alone would not have been sufficient to affirm the exclusion of his testimony.[11] Thus, if the Court rules for petitioners on the question presented, petitioners would be entitled to vacatur of the summary judgment in favor of P&G.

It has been nearly 20 years since this Court decided *Joiner*, the last case in the "*Daubert* trilogy." In that time, the federal circuits have divided sharply on the proper standard for the admissibility of expert opinions on general causation. This Court should grant certiorari to resolve that conflict and to reiterate the proper limits on courts' gatekeeping role with respect to scientific issues on which reasonable experts disagree.

CONCLUSION

The petition for a writ of certiorari should be granted.

---

[11] In the Eleventh Circuit, as in other circuits, such criticisms "speak to the weight to be afforded [the expert's] testimony, not its admissibility." *Southern States Coop., Inc. v. Melick Aquafeeds, Inc.*, 476 F. App'x 185, 189 (11th Cir. 2012) (per curiam); *see also*, *e.g.*, *Kudabeck v. Kroger Co.*, 338 F.3d 856, 861-62 (8th Cir. 2003) (it is well-settled that "attacks regarding the completeness of [a differential diagnosis] go to the weight and not the admissibility of [the expert's] testimony"); *Best v. Lowe's Home Ctrs., Inc.*, 563 F.3d 171, 182 (6th Cir. 2009) (same).

Respectfully submitted,

RAYMOND C. SILVERMAN
MELANIE H. MUHLSTOCK
MATTHEW J. MCCAULEY
PARKER WAICHMAN LLP
6 Harbor Park Drive
Port Washington, NY 11050
(516) 466-6650

DAVID C. FREDERICK
Counsel of Record
DEREK T. HO
KELLOGG, HUBER, HANSEN,
TODD, EVANS & FIGEL,
P.L.L.C.
1615 M Street, N.W.
Suite 400
Washington, D.C. 20036
(202) 326-7900
(dfrederick@khhte.com)

February 6, 2015